Atty. Dkt. No. 029318-0107

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Bosch et al.

\_\_Title:

STERILE FILTERED
NANOPARTICULATE
FORMULATIONS OF
BUDESONIDE AND
RECLOMETHASONE H

BECLOMETHASONE HAVING TYLOXAPOL AS A SURFACE

**STABILIZER** 

Appl. No.:

10/035,324

Filing

01/04/2002

Date:

Examiner:

Art Unit: Not Yet Assigned

Not Yet Assigned

## UNDER 37 CFR § 1.56

Commissioner for Patents Box PATENT APPLICATION Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of a document known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed document is being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Michele M. Simkin

Attorney for Applicant Registration No. 34,717

Date March 18, 2003

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PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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				U.S. PATENT DOCUMENTS	3	
Examiner Initials*		U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant
	Cite No. <sup>1</sup>	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	For Office <sup>3</sup>	eign Patent [ Number⁴	Ocument Kind Cod (if known	_	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>		
	89	Jacobs, Claudia, et al. "Production and Charafterization of a budesonide Nanosuspension for Pulmonary Administration", <i>Pharmaceutical Research</i> , Vol. 19, No. 2, February 2002.	Ŷ		

Examiner Signature	Date Considered

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.